

AD_____

Award Number: DAMD17-03-1-0082

TITLE: Prevalence and Outcomes of Restless Legs Syndrome Among
Veterans

PRINCIPAL INVESTIGATOR: Claire C. Bourguet, Ph.D.

CONTRACTING ORGANIZATION: Northeastern Ohio Universities
Rootstown, Ohio 44272

REPORT DATE: February 2004

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

BEST AVAILABLE COPY

20040706 122

REPORT DOCUMENTATION PAGEForm Approved
OMB No. 074-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503

1. AGENCY USE ONLY (Leave blank)		2. REPORT DATE February 2004	3. REPORT TYPE AND DATES COVERED Annual (1 Feb 2003 - 31 Jan 2004)	
4. TITLE AND SUBTITLE Prevalence and Outcomes of Restless Legs Syndrome Among Veterans			5. FUNDING NUMBERS DAMD17-03-1-0082	
6. AUTHOR(S) Claire C. Bourguet, Ph.D.				
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Northeastern Ohio Universities Rootstown, Ohio 44272 <i>E-Mail:</i> bourguet@neoucom.edu			8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012			10. SPONSORING / MONITORING AGENCY REPORT NUMBER	
11. SUPPLEMENTARY NOTES				
12a. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited				12b. DISTRIBUTION CODE
13. ABSTRACT (Maximum 200 Words) Background: Restless Legs Syndrome (RLS) is a commonly under or misdiagnosed organic cause of insomnia. Prevalence estimates range from 4 to 16%, with 29% reported among Veterans. Thirty-five percent of US adults report insomnia annually. There is evidence that insomnia leads to psychic distress which impacts health care utilization. Purpose: To examine components of a proposed model linking RLS to insomnia, and insomnia to psychic distress and increased utilization. Scope: To estimate the prevalence of RLS, insomnia, mood disorders, and substance abuse; quantify the proportion of mood disorders and substance abuse which are attributes to RLS and insomnia; document the diagnosis of RLS and insomnia; and estimate the association of RLS and insomnia to health care utilization and health related quality of life. Methods: A cross-sectional survey of a representative sample of Ohio VA clients using telephone interviews and data extracted from medical records. One year follow-up of health care utilization using postal questionnaire and medical records. Results: In the first research year, interviews were completed with 958 veterans. Methods for abstracting utilization data from electronic medical records were developed, as were methods to adjust study outcomes for health status of study members. Data collection is ongoing.				
14. SUBJECT TERMS Restless legs syndrome, insomnia, depression, mood disorders, utilization, veterans				15. NUMBER OF PAGES 43
				16. PRICE CODE
17. SECURITY CLASSIFICATION OF REPORT Unclassified	18. SECURITY CLASSIFICATION OF THIS PAGE Unclassified	19. SECURITY CLASSIFICATION OF ABSTRACT Unclassified	20. LIMITATION OF ABSTRACT Unlimited	

NSN 7540-01-280-5500

Standard Form 298 (Rev. 2-89)
Prescribed by ANSI Std. Z39-18
298-102

Table of Contents

Cover.....	1
SF 298.....	2
Introduction.....	4
Body of report	5
Key Research Accomplishments.....	11
Reportable Outcomes.....	11
Conclusions.....	11
References.....	11
Appendices.....	12

Abstracts accepted for presentation

Manual of Operations

INTRODUCTION

Restless Legs Syndrome (RLS) is a sensori-motor disorder characterized by unpleasant, abnormal feelings in the legs and occasionally arms which occur at rest and when initiating sleep. The sufferer experiences an uncontrollable urge to move in order to relieve symptoms. RLS interferes with the ability to fall asleep or to maintain sleep. The resulting sleep deprivation can interfere with family life, social activities, and job performance. (1) We hypothesize that RLS has a high prevalence in the veteran community and is under diagnosed. We also hypothesize that undiagnosed and untreated RLS is associated with an unknown, but measurable proportion of the insomnia in any population. An association between insomnia and mood and anxiety disorders is well documented, as is the association between these mental health disorders and increased health care utilization. (2;3) In this research, we therefore propose an underlying model in which RLS contributes to insomnia; and insomnia contributes to diminished mental health status. Diminished mental health status in turn may lead to increased health care utilization.

The current research is a study of the prevalence and outcomes of RLS among patients of the Veterans Administration health care system in northern Ohio. The specific goals of the research are the following:

To estimate the prevalence of Restless Legs Syndrome and insomnia.

To determine in the VA population the proportion of insomnia that is attributable to RLS;

To estimate in the VA population the strength of the association of insomnia and RLS with depression, anxiety, and substance abuse adjusting for comorbid health conditions;

To estimate in the VA population strength of the association of insomnia and RLS with health related quality of life adjusting for comorbid conditions;

To document the current level of diagnosis of insomnia and RLS in the VA population;

- To document the level of health care utilization at baseline interview and at one year follow-up associated with insomnia and RLS adjusting for comorbid health conditions.
- To assess the validity of the questionnaire instrument using interview by a trained clinician as the gold standard.

BODY OF REPORT

Statement of Work

The following is the revised statement of work which was submitted on December 18, 2002 and approval by email on February 6, 2003. Tasks which were planned for Year 1 of the project are indicated in bold type. The report of our accomplishments with regard to the items indicated in bold type follows.

Task 1: Estimate the prevalence of Restless Legs Syndrome, insomnia, mood and anxiety disorders, and substance abuse in persons who have scheduled primary care appointments at a Veterans Administration Community Based Outpatient Clinic (CBOC) in northeast Ohio. Document the current level of diagnosis of insomnia and RLS in the VA population.

- a) **Hire and train study personnel (Months 1-2)**
- b) **Recruit 1914 study members at CBOC's (Months 3-8)**
- c) **Conduct computer assisted telephone interviews with 1914 Veterans Administration clients. (Months 4-10)**
- d) **Extract problem lists and time 1 utilization data from 1914 electronic medical records. (Months 6-12)**
- e) Data cleaning and analysis (Months 13-21)
- f) Manuscript preparation (Months 20-24)

Task 2: Estimate in the northern Ohio VA population the strength of the association of RLS with insomnia after adjusting for comorbid health conditions. Determine the proportion of insomnia that is attributable to RLS. Estimate in the VA population the strength of the association of insomnia with depression, anxiety, and substance abuse adjusting for comorbid health conditions. Determine the proportion of psychic distress that is attributable to insomnia. Estimate in the VA population strength of the association of insomnia and RLS with health related quality of life adjusting for comorbid conditions.

- a) Data analysis (Months 22-30)
- b) Manuscript preparation (Months 30-36)

Task 3: Document the level of health care utilization at baseline interview and at one year follow-up associated with insomnia and RLS adjusting for comorbid health conditions.

- a) **Conduct interviews by mail with 1914 VA clients to determine health care utilization one year after baseline interview. (Months 16-23)**
- b) **Extract time 2 utilization data from 1914 electronic medical records (Months 16 - 23)**
- c) **Data entry, cleaning, and analysis (Months 18 - 30)**
- d) **Manuscript preparation (Months 30 - 36)**

Task 4: Assess the validity of the RLS questionnaire using interview by a trained clinician as the gold standard.

- a) **Recruit study members who are patients at the Akron CBOC and conduct clinical assessment (Months 7 - 18)**
- b) **Analyze data (Months 19 - 20)**
- c) **Manuscript preparation (Months 21 - 24)**

Task 5: Assess the external validity of the study sample with respect to the population of VA patients who have had a visit in the past year.

- a) Extract population data from electronic patient record system (Months 13-14)
- b) Data analysis (Months 15-16)
- c) Manuscript preparation is part of *Task 1*.

ACCOMPLISHMENTS IN YEAR 1 OF THE RESEARCH.

This year has been devoted to hiring and training the research team and to data collection.

Task 1.a Hire and train study personnel (Months 1-2). A full time research coordinator, Kristin Baughman, Ph.D., one full time recruiter/interviewer and four part time recruiter/interviewers have been hired and trained.

All study personnel have completed the required training for research with human subjects, HIPAA training, and good clinical practice and VHA privacy policy training. The research coordinator and two recruiter/interviewers attended training on the WHO Composite International Diagnostic Index (CIDI)(4) offered by the Institute for Social Research at the University of Michigan at Ann Arbor, MI. All recruiter/interviewers have been trained by the research coordinator on all aspects of the data collection protocol.

A *Manual of Operations* for the research was developed. A copy of the manual is included in the Appendices.

Task 1.b Recruit 1914 study members at Community Based Outpatient Clinics (Months 3-8).

Task 1.c Conduct computer assisted telephone interviews with 1914 Veterans Administration clients. (Months 4-10).

Final approval from the USAMRMC Human Subjects Research Review Board was received on May 30, 2003 at which date we began recruiting study members.

As of February 5, 2004, 958 veterans have been recruited and interviewed for the research. An additional 188 veterans were recruited and signed consent forms but declined to participate when contacted for the telephone interview. Table 1 shows the age and gender distribution of these study members along with the final required sample size in each age/ gender group.

We have also done some preliminary calculations of RLS prevalence based on the data that were available in December, 2003. On the basis of the those prevalence estimates, we have

slightly adjusted our required sample size. The new sample sizes are shown in the 4th column of Table 1.

	Age Group	Original Sample Size	Adjusted Sample Size	Completed Interviews	Additional Number Required
Men	18-30	115	115	8	107
	31-40	177	177	25	152
	41-50	177	217	81	136
	51-60	236	254	164	90
	61-70	236	217	165	52
	71-80	236	236	192	44
	81 +	290	254	211	43
Women	18-50	157	217	53	164
	51+	290	290	59	231
Total		1914	1977	958	1019

Table 1. Completed interviews (February 5, 2004)

The "Additional number required" in the last column of the table shows that we are having difficulty recruiting younger men and women of all ages. We have analyzed the recruiting process and have concluded that patients in these demographic groups are more likely to leave the CBOC's without speaking to a recruiter.

We have developed two approaches to meeting our required sample size. First, we have proposed a revision to our recruiting protocol in order to improve the success rate with younger men and with women. Our current recruiting approach involves preselecting potential study members and approaching them in the CBOC waiting rooms for recruiting. We have proposed to change the recruiting procedure to telephone potential study members in these groups the day before their office visit. The telephone call will briefly introduce the research and, hopefully, improve our recruiting success. Women are more likely than other groups to agree to participate if we have an opportunity to explain the study to them.

This change to the recruiting protocol has been approved by the Institutional Review Boards for the Protection of Human Subjects at NEOUCOM and at the Cleveland Veterans Affairs Medical Center. The change was submitted to the USAMRMC Human Subjects Research Review Board on September 2, 2003. We are waiting for approval of the protocol change from the USAMRMC Board and we have not yet implemented the change.

Second, we recognized that additional funding would be required to support data collection to reach our planned sample size. On January 29, 2004, we received an additional unrestricted grant from Pfizer Pharmaceutical Corporation Research Foundation. These funds will be used to support our recruiting and interviewing efforts. The funding request to Pfizer was based on our rate of recruiting and interviewing up to August, 2003.

Task 1.d Extract problem lists and time 1 utilization data from 1914 electronic medical records. (Months 6-12).

Information from each participant's medical records will be extracted from the Computerized Patient Record System (CPRS). CPRS is a computer application of the Veterans Health Information Systems and Technology Architecture (VISTA). The medical record includes information on all physician visits, diagnoses, medications, test results, and referrals.

Patients will be matched with their medical information using the patient's birth date and VA identification number (first letter of last name followed by last 4 digits of social security number).

The following information will be obtained from the Reports folder and the clinical reports subfolder in CPRS.

Medications active at the time of the interview (under the Outpatient Rx Profile folder)
Date of prescription
Quantity
Status of prescription (active, suspended, discontinued, or expired)
Clinic visits completed in the month prior to the interview (under the Past Clinic Visits folder)
Type of appointment: lab, radiology, primary care, mental health, physical therapy, optometry, podiatry, etc.
Date of appointment
Admissions to VA facility in the month prior to the interview (under Admissions folder)
Date of admission
Date of discharge
Procedures and surgeries in the month prior to the interview (under ICD Procedures and ICD Surgeries folders)
ICD code
Date of procedure or surgery
Problems active at the time of the interview (under the Problems List folder)
Description of problems
ICD-9 codes
Onset dates
Last updated dates
Location (clinic, department, physician or medical team)
Laboratory tests (under the Laboratory & Lab orders folders)
Lab tests within the month prior to the interview
Date of tests
Radiology visits (under radiology folder)
Imaging reports within the month prior to the interview
Referrals within and outside of the VA (under Referrals folder)
Date referral was made.
Health care specialty referred to.
Date patient was seen by consultant.
Consultant report

This information will be transferred from the VISTA CPRS software (the computerized medical record) to an MS Access database using VA FileMan software. FileMan is VISTA's database management system. Queries can be written to extract this data in batch mode.

Problems active at the time of interview will be used to adjust the relationship between independent variables (RLS and Insomnia) and dependent variables (mental health status and health care utilization) for comorbid conditions (case-mix adjustment, a component of Task 2). Utilization data from the medical record are a study outcome included in Task 3.

Task 4.a Recruit study members who are patients at the Akron CBOC and conduct clinical assessment (Months 7 - 18).

This task is the data collection phase of the "Validation Substudy" in which we will evaluate the sensitivity and specificity of the RLS questionnaire in our VA population. After discussion with Robin Dillner, who was the Human Subjects Protection Scientist, originally assigned to review of our project, we submitted the "Validation Substudy" as an amendment to the main proposal.

The materials for review of the amendment were submitted to the USAMRMC Human Subjects Research Review Board on April 16, 2003. Ms. Dillner has left the USAMRMC and the review of the amendment has assigned to Maryann F. Pranulis, DNSc. The review is still pending and data collection has not begun.

Activities in preparation for year 2

We have obtained a commitment of a sufficient number of newsletters for all study participants from the National Sleep Foundation. This glossy 20 page newsletter, *SleepMatters*, is published quarterly by the National Sleep Foundation. It contains a wealth of information about sleep topics and is not restricted to RLS. These newsletters will be mailed by our office to all study participants with a cover letter explaining that they have been provided complements of the VA sleep research program. The cover letter will also give participants an update on the progress of the research. This method is used to increase the response rate for the one year follow-up.

In year 2, we will conduct the data analysis for Task 2. This task calls for the use of techniques for case-mix adjustment. We have been exploring the available software options to determine which is most appropriate to the goals and context of our research.

The following summarizes our current thinking about this issue.

Notes on Johns-Hopkins ACG, Medicare, and DxCG Case-Mix Adjustment Methods

The following discussion compares the approaches of three case-mix adjustment methods with available software. The input data for each patient that are required by all three methods are essentially the same: a patient identification code, gender, age (or DOB), and ICD-9 codes. All three methods then take this information and create various levels of patient groupings based on diagnoses, which are then input, along with age and gender, into regression models to predict health care costs at the patient level.

The patient groups produced by the Johns-Hopkins software are called Adjusted Clinical Groups (ACG) and represent aggregations of possibly unrelated diagnoses that tend to result in similar health care costs. The Medicare and DxCG software produce nearly identical patient groupings, which also reflect potential costs, but are generally composed of more medically related diagnoses.

The Johns-Hopkins ACG software and the DxCG, Inc. software are commercial products, which are available to academic researchers for a licensing fee of \$750. The ACG license is limited to a 2-year term; the DxCG license runs the duration of the research project. The Medicare software is publicly available at no charge as a download from the Centers for Medicare & Medicaid Services (CMS) web site (<http://www.cms.hhs.gov/healthplans/rates/>). The Medicare HCC software uses only 70 of the 184-189 Hierarchical Condition Categories (HCC); however, a comment line in the SAS macro mcmshier file (part of the software) states: "see complete version HCCHRV12 and modifying program CMSHIER." Thus, software coding all the HCC is apparently available from CMS. This is being investigated.

DxCG produces a patient-level relative risk score (RR), which is the predicted cost score / average cost for a benchmark population. We could get an average annual cost for a VA outpatient population and either 1) compute RR using predicted costs from Medicare model or 2) build our own model using HCC and demographic data, but based on VA cost data. For 2) we would need cost¹, diagnosis, and demographic data from Vista on a broader sample of outpatients than those consented for our study.

The above discussion presupposes that we will use the relative risk score for case-mix adjustment, which is an attractive idea (single variable). However, this is a change from our original plan. Initially, we planned to use diagnosis group indicator variables (like ACG, DCG, or HCC) in regression models. If we proceed with this method, the Medicare hcc software may be adequate, especially using the complete version. The Medicare software produces HCC that are the same, or very nearly the same, clusterings of ICD-9 codes used by DxCG.

Cost models may still be useful for another purpose: assessing the cost of undiagnosed and untreated RLS. Suppose we took those patients who, based on the criteria we are using, have RLS and create a new "what if" data set with their diagnoses of insomnia and/or depression removed (or remove these diagnoses for a proportion of the RLS cases²). Then predict their health costs based on their other problems, but as if they no longer had insomnia and/or depression because their RLS is managed. The difference in predicted cost would be a measure of the VA savings that could be realized if RLS is diagnosed and treated. A VA-specific model, as in 2) above, may be more useful for this purpose.

The remaining issues now being investigated are:

1. Whether the Johns-Hopkins ACG diagnosis grouping methodology or the Medicare/DxCG methodology is more appropriate for case-mix adjustment, given the objectives of our research.
2. Whether only diagnosis group variables are needed, or whether predicted patient-level costs are needed also.
3. If predicted patient-level costs are desirable, which benchmark population is best suited to the needs of this research: that used by Johns-Hopkins ACG, DxCG, or Medicare—or should a VA outpatient-specific benchmark population be used and are the data available to do this.

¹Cost data may not be directly available in Vista, since the VA is both "insurer" and provider, but a standardized surrogate measure may be available.

²The proportions of insomnia and depression attributable to RLS could be used.

KEY RESEARCH ACCOMPLISHMENTS

Recruited and interviewed 958 study members.

REPORTABLE OUTCOMES

Abstract accepted for poster presentation at the meeting of the Associated Professional Sleep Societies (APSS) meeting, Philadelphia, June, 2004 and to be published in a special issue of the Journal, *Sleep*. (Abstract is included in the Appendix).

Abstract accepted for poster presentation at the Peer Reviewed Medical Research Program Military Health Research Forum (Investigators' Meeting), San Juan, Puerto Rico, April, 2004. (Abstract is included in the Appendix).

Abstract accepted for presentation at the Research and Education Forum of the Ohio Academy of Family Physicians, Columbus, Ohio, April, 2003. (Abstract is included in the Appendix).

CONCLUSIONS

As data collection is still underway, there are no scientific conclusions at this time.

REFERENCES

Reference List

(1) National Institute of Neurological Disorders and Stroke. Restless Legs Syndrome Fact Sheet. 2001. NIH Publication No.01-4847.

Ref Type: Pamphlet

(2) Benca RM. Consequences of insomnia and its therapies. *J Clin Psychiatry* 2001; 62 Suppl 10:33-38.

(3) Stoller MK. Economic effects of insomnia. *Clin Ther* 1994; 16(5):873-897.

(4) Kessler RC, Andrews G, Mroczek D, Ustun B, Wittchen HU. The World Health Organization Composite International Diagnostic Interview Short Form (CIDI-SF). *International Journal of Methods in Psychiatric Research* 1998; 7(4):171-185.

APPENDICES

- 1. Abstracts accepted for presentation at scientific meetings.**
- 2. Manual of Operations.**

APPENDIX 1

1. Abstracts accepted for presentation at scientific meetings.

Abstract accepted for poster presentation at the Associated Professional Sleep Societies meeting, June, 2004.

The Prevalence and Outcomes of Restless Legs Syndrome among Veterans.

Ober SK, Bourguet CC, Baughman KR, Steiner RP, and Shapiro, HD.

Introduction: Restless Legs Syndrome (RLS) is a sensori-motor disorder characterized by unpleasant, abnormal feelings in the legs and occasionally arms which occur at rest or when initiating sleep, and in the evening or at night. Sufferers experience an uncontrollable urge to move to relieve these symptoms. RLS interferes with the ability to fall asleep or maintain sleep. Estimates of the prevalence of RLS in community populations ranges from 4% to 17%. A 29% prevalence has been reported in one VA outpatient sample. The goal of this research is to estimate the prevalence of RLS and insomnia among patients seen at VA primary care clinics. This research investigates an explanatory model in which RLS contributes to insomnia. Insomnia contributes to diminished mental health status and to increased health care utilization.

Methods: Study members were a representative sample of Veterans seen at Community Based Outpatient Clinics affiliated with the Louis B. Stokes Cleveland VA Medical Center in Ohio. A cross-sectional telephone survey was used to determine the prevalence of RLS and insomnia. Patients were classified as non-RLS cases, probable (3 criteria) or definite (4 criteria) cases. Health status was measured using the Mental and Physical Composite Scales (MCS and PCS) of the SF12. Utilization information was obtained from the patient and included: number of office visits, diagnostic procedures, hospitalizations, and surgical procedures. All tests of hypothesized relationships were adjusted for age, gender, Body Mass Index, and physical health status (PCS score). **Results:** Preliminary results from 620 patients are reported. Forty-five percent of patients who were approached completed an interview. The sample included 544 men and 76 women, age range 25 to 89 years. Among men, the prevalence of probable RLS was 15.8%, definite RLS was 9.7%, moderate insomnia was 9.9% and severe insomnia was 3.3%. Among women, the prevalence of probable RLS was 19.7%, definite RLS was 14.5%, moderate insomnia was 26.3%, and severe insomnia was 7.9%. The insomnia score of an average patient increased 53% in the presence of 4 RLS symptoms ($p < .001$). In this VA sample, the mean MCS score was 50.3, similar to the US population mean. The mean PCS score was 39.9, one standard deviation below the US mean. The mean MCS score of persons with probable or definite RLS was significantly lower (41.0, $p < .01$), as was the mean MCS score of persons with moderate insomnia (40.6, $p < .0001$) and of persons with severe insomnia (34.7, $p < .0001$). As hypothesized, the association between RLS and the MCS disappeared when insomnia was included in the regression model. Analysis of utilization data obtained from patients found that neither insomnia nor RLS were associated with physicians visits. RLS but not insomnia was positively associated ($p = .04$) with diagnostic testing. **Conclusions:** Preliminary analysis of approximately one third of the planned sample offered support for the hypothesized explanatory model. The final sample ($n=1914$) will allow precise estimates of RLS prevalence in age strata. **Support:** Supported by the US Army Medical Research and Materiel Command under DAMD17-03-1-0082.

Abstract accepted for poster presentation at Peer Reviewed Medical Research Program Military Health Research Forum (Investigators' Meeting), San Juan, Puerto Rico, April, 2004.

THE PREVALENCE AND OUTCOMES OF RESTLESS LEGS SYNDROME AMONG VETERANS. Bourguet CC, Ober SK, Baughman KR, Steiner RP, Shapiro, HD. The Northeastern Ohio Universities College of Medicine.

BACKGROUND/ PURPOSE: Restless Legs Syndrome (RLS) is a sensori-motor disorder characterized by unpleasant, abnormal feelings in the legs and occasionally arms which occur at rest or when initiating sleep, and in the evening or at night. The sufferer experiences an uncontrollable urge to move in order to relieve these symptoms. RLS interferes with the ability to fall asleep or maintain sleep. Estimates of the prevalence of RLS in community populations ranges from 4% to 17%. A 29% prevalence has been reported in one VA outpatient sample. The goal of this research is to estimate the prevalence of RLS and insomnia among patients seen at VA primary care outpatient clinics. This research investigates an explanatory model in which RLS contributes to insomnia. Insomnia contributes to diminished mental health status, and diminished mental health status leads to increased health care utilization. **METHODS:** Study members are a representative sample (final sample size = 1914) of Veterans seen at Community Based Outpatient Clinics affiliated with the Louis B. Stokes Cleveland VA Medical Center in Ohio. A cross-sectional telephone survey is being used to determine the prevalence of RLS and insomnia. Patients are classified as non-RLS cases, probable (3 criteria) or definite (4 criteria) cases. Health measures include the Mental and Physical Composite Scales (MCS and PCS) of the SF12, the WHO's Composite International Diagnostic Index (Short Form), and the problem list from the medical record. Utilization measures will be obtained from the patient and the medical record and include: number of office visits, diagnostic procedures, prescribed medications, hospitalizations, and surgical procedures. Additional utilization data will be collected at one year follow-up. All data analysis includes adjustment for age, gender, Body Mass Index, and physical health status (PCS score). **RESULTS:** Preliminary results from 620 patients are reported here. Forty-five percent of patients who were approached completed an interview. The sample includes 544 men and 76 women, age range 25 to 89 years. Among men, the prevalence of probable RLS is 15.8%, definite RLS is 9.7%, moderate insomnia is 9.9% and severe insomnia is 3.3%. Among women, the prevalence of probable RLS is 19.7%, definite RLS is 14.5%, moderate insomnia is 26.3%, and severe insomnia is 7.9%. The insomnia score of an average patient increases 53% in the presence of 4 RLS symptoms ($p < .001$). In this VA sample, the mean MCS scores is 50.3, similar to the US population mean. The mean PCS score is 39.9, one standard deviation below the US mean. The mean MCS score of persons with probable or definite RLS is significantly lower (41.0, $p < .01$), as is the mean MCS score of persons with moderate insomnia (40.6, $p < .0001$) and of persons with severe insomnia (34.7, $p < .0001$). As hypothesized, the association between RLS and the MCS disappears when insomnia is included in the regression model. Analysis of utilization data obtained from patients finds that neither insomnia nor RLS is associated with physicians visits. RLS but not insomnia is positively associated ($p = .04$) with diagnostic testing. **CONCLUSION:** Preliminary analysis of approximately one third of the planned sample offers support for the hypothesized explanatory model. The final sample will allow precise estimates of RLS prevalence in age strata. Data obtained from medical records will allow improved adjustment for health status and more definitive conclusions about the relationship between sleep disorders and health care utilization.

THE U.S. ARMY MEDICAL RESEARCH MATERIEL COMMAND UNDER DAMD17-03-1-0082 SUPPORTED THIS WORK.

Abstract accepted for presentation at the Research and Education Forum of the Ohio Academy of Family Physicians, Columbus, Ohio, April, 2003.

The Prevalence and Outcomes of Restless Legs Syndrome among Patients at VA Primary Care Clinics. Baughman K., Panzner M., Ober S., Bourguet C., Steiner R. Louis Stokes Department of Veterans Affairs Medical Center, Brecksville, OH 44141

Introduction: Restless Legs Syndrome (RLS) is a sensori-motor disorder characterized by unpleasant, abnormal feelings in the legs and occasionally arms which occur at rest or when initiating sleep, and in the evening or at night. RLS interferes with the ability to fall asleep or maintain sleep. The goal of this research is to estimate the prevalence of RLS and insomnia among patients seen at VA primary care clinics. This research investigates an explanatory model in which RLS contributes to insomnia. Insomnia contributes to diminished mental health status and to increased health care utilization. **Methods:** Study members were representative of Veterans seen at primary care clinics affiliated with the Cleveland VA Medical Center. A telephone survey was used to determine the prevalence of RLS and insomnia. Patients were classified as non-RLS cases, probable or definite cases. Health status was measured using the Mental and Physical Composite Scales (MCS and PCS) of the SF12. Utilization information was obtained from the patient and included: number of office visits, diagnostic procedures, hospitalizations, and surgical procedures. All tests of hypothesized relationships were adjusted for age, gender, Body Mass Index, and physical health status (PCS score). **Results:** Preliminary results from 620 patients are reported. Forty-five percent of patients who were approached completed an interview. The sample included 544 men and 76 women, age range 25 to 89 years. Among men, the prevalence of probable RLS was 15.8%, definite RLS was 9.7%, moderate insomnia was 9.9% and severe insomnia was 3.3%. Among women, the prevalence of probable RLS was 19.7%, definite RLS was 14.5%, moderate insomnia was 26.3%, and severe insomnia was 7.9%. The insomnia score of an average patient increased 53% in the presence of definite RLS ($p < .001$). The mean MCS score was 50.3, similar to the US population mean. The mean PCS score was 39.9, one standard deviation below the US mean. The mean MCS score of persons with probable or definite RLS was significantly lower (41.0, $p < .01$), as was the mean MCS score of persons with moderate insomnia (40.6, $p < .0001$) and of persons with severe insomnia (34.7, $p < .0001$). As hypothesized, the association between RLS and the MCS disappeared when insomnia was included in the regression model. Analysis of utilization data obtained from patients found that neither insomnia nor RLS was associated with physicians visits. RLS but not insomnia was positively associated ($p = .04$) with diagnostic testing. **Conclusions:** Preliminary analysis of approximately one third of the planned sample offered support for the hypothesized model in which RLS impacts health outcomes and utilization through insomnia. **Support:** Supported by the US Army Medical Research and Materiel Command under DAMD17-03-1-0082.

APPENDIX 2

**Veterans Sleep Study:
The Prevalence of Restless Legs Syndrome**
Manual of Operations

Northeastern Ohio Universities College of Medicine

Louis B. Stokes Cleveland Veterans Administration Medical Center

University of Akron

May 2003

Table of Contents

	Page
1. Trial Objectives	3
2. Proposal Abstract	3
3. Sequence of Events	3
4. CBOC Protocol Negotiation	4
5. Patient Recruitment	4
6. Patient Eligibility	5
7. Ethics and Confidentiality	6
8. Building Rapport with Patients	6
9. Answering Patients' Questions	7
10. Distressed Patients	7
11. Baseline Telephone Interviews	9
12. Confidential Database	9
13. Computer File Backup Policy	9
14. Interview Quality Control	10

APPENDICES

Appendix A Study Recruitment Brochure	
Appendix B CBOC Profile Form	
Appendix C Patient Recruitment Form	
Appendix D Clock Drawing Test	
Appendix E Consent and HIPAA Forms	
Appendix F Scheduling Form	
Appendix G Patient Reminder Card	
Appendix H Suicide Protocol	
Appendix I Interviewer QC Checklist	

1. Study Objectives

To examine the components of a proposed model which links Restless Legs Syndrome (RLS) to insomnia, and insomnia to psychic distress and to health care increased utilization. The goals of the research are the following:

- To estimate the prevalence of Restless Legs Syndrome and insomnia.
- To determine in the VA population the proportion of insomnia that is attributable to RLS;
- To estimate in the VA population the strength of the association of insomnia and RLS with depression, anxiety, and substance abuse adjusting for comorbid health conditions;
- To estimate in the VA population strength of the association of insomnia and RLS with health related quality of life adjusting for comorbid conditions;
- To document the current level of diagnosis of insomnia and RLS in the VA population;
- To document the level of health care utilization at baseline interview and at one year follow-up associated with insomnia and RLS adjusting for comorbid health conditions.
- To assess the validity of the questionnaire instrument using interview by a trained clinician as the gold standard.

2. Proposal Abstract

Background. Prevalence estimates for Restless Legs Syndrome (RLS) range between 4 and 16%, with 29% reported in one VA sample. RLS is a recognized organic cause of insomnia which is commonly under or misdiagnosed. Thirty-five percent or more of US adults report insomnia each year. There is good evidence that insomnia leads to psychic distress which contributes to health care utilization.

Objective/Hypothesis. To examine the components of a proposed model which links RLS to insomnia, and insomnia to physic distress and to health care increased utilization.

Specific aims. We will estimate the prevalence of RLS and insomnia; quantify the proportion of mood disorders and substance abuse which are attributable to RLS and insomnia; document the level of diagnosis of RLS and insomnia; and estimate the strength of the association of RLS and insomnia to health care utilization and reduced health related quality of life.

Study design. A cross-sectional prevalence survey of a random sample of northern Ohio VA patients using computer assisted telephone interviews and data extracted from VA medical records. One year follow-up of health care utilization using postal questionnaire and medical records.

Relevance. In this population, a high prevalence of mood disorders and substance abuse is well documented. RLS, for which pharmacologic treatment is available, may contribute to the level of morbidity. Documentation of a high prevalence of RLS in the VA population and of the validity of the hypothesized model can lead to increased awareness of a treatable cause of psychic distress. Improved awareness of RLS and insomnia may lead to diagnosis and treatment with resulting improvement in mental health status and decreasing health care utilization.

3. Sequence of Events

Hire and train study personnel (1st two months)

- Hire 2 recruiter/interviewers and 1 project coordinator
- VA new employee training by Research Administration
- Human Subjects Research training and exams
- HIPAA training (and VA HIPAA Minutes)
- CIDI training at University of Michigan
- Good Clinical Practice training
- Questionnaire and Epi Info training

- Review National Sleep Foundation and RLS websites

Telephone computer-assisted interviews (1st year):

- Negotiate protocol logistics with Community Based Outpatient Clinic (CBOC) directors for patient recruitment
- Recruit 1,914 patients from CBOC waiting rooms
- Obtain informed consent and schedule telephone appointments
- Administer computer-assisted interviews over the telephone within 7-14 days of recruitment

Extract problem lists and utilization data from 1,914 electronic medical records (1st two years):

- Extract Time 1 data in first year
- Extract Time 2 data in second year

Validation of study instruments (1st two years):

- Conduct clinical evaluations on the 197 participants from the Akron CBOC

Mail Surveys on health utilization (2nd year):

- Send a mail questionnaire to the 1,914 study participants
- Conduct reminder phone calls for questionnaires not returned promptly

Data Analysis & Manuscript preparation (2nd and 3rd years):

4. CBOC protocol negotiation

We will meet with each CBOC director to negotiate logistical details for recruitment at his or her clinics. We will adapt our recruitment strategy to the routine operations and physical space available at each study site. We also will obtain the names of each clinic's nurse manager and PCAS manager. A study brochure for clinic personnel has been designed to explain what the study is about and to describe how they can assist us in recruiting patients (see Appendix A).

Our objective is to work up a plan that will allow us to recruit veterans while impacting the participating CBOC as little as possible and protecting the privacy of the veteran.

Kris Baughman will obtain information to fill out a CBOC profile form (see Appendix B) that she will distribute to the research assistants.

5. Patient Recruitment

Kris Baughman will generate a list of patients with primary care appointments for a given recruitment day. She will select patients based on the time of their appointment, their gender, and their age. First priority will be given to women over the age of 50 and men under the age of 31 (two groups that will be difficult to recruit since they form a small percentage of primary care patients at the VA). This list, along with a separate recruitment form for each patient to be approached (see Appendix C) will be given to the research assistants assigned to recruit patients for that day.

At the beginning of the recruitment day the research assistants will tag the medical file of each patient whom has been selected by Kris. This will alert the receptionist who checks out patients to ask the patient to speak with us before leaving the clinic. A research assistant will approach the patient and briefly describe the study and ask if the patient is interested in participating. If the patient agrees to participate (or wants to learn more about the study), the research assistant will take the patient to a private room to discuss the consent form. If the room is currently in use, the research assistant will give a copy of the consent form to the patient to read while waiting in the waiting room. If more than one patient is waiting to speak with us, women over age 50 and men under age 30 will be given priority. If there are

no women over 50 or men under 30, then the patient who had the earliest appointment that day will be selected next. If two patients had appointments at the same time, then the patients will be chosen alphabetically by their first name.

On the way to the private room, the research assistant will ask, "Is someone waiting here for you or did you drive yourself here, today?" If the patient has a caregiver who drove him or her to the appointment, the patient will be asked to draw a picture of a clock face with the time that they normally go to sleep at night. If the patient is competent (i.e., they can accurately draw a clock face) the research assistant will go on to describe the consent form. If the patient is not competent, then the research assistant will thank the patient for participating and escort them back to the waiting room. Appendix D has a complete listing of criteria for the clock face test.

If the patient drove him/herself to the appointment, the research assistant will omit the competency test (the clock test) and give the patient more information about the study and consent form. Research assistants should introduce the consent form to the respondent by saying:

"Before we can call you for the telephone survey, we need to go over a consent form which is required by the VA medical center. The consent form describes the study, as well as your rights as a participant in it. In order to participate, you need to sign this consent form and initial each page. I will give you an extra copy of the form before you leave. Do you have any questions?"

Research assistants should be prepared to explain/paraphrase the content of each page for patients who request assistance. The consent form must be signed by the patient, a witness (usually, the other research assistant), the research assistant who conducted the consent process, and initialed by the patient on each page. A copy is then given to the patient to take home.

The consent form has been approved by the NEOUCOM, Cleveland Veterans Administration Medical Center (VAMC), and Department of Defense (DOD) IRBs (see Appendix E). The consent form explains the study. By signing the consent form, the patient indicates his or her willingness to participate. The research assistant will give a copy of the consent form to the patient. One signed copy is returned to the project office.

If the patient does not have time to carefully read the consent form, you may send the form home with the patient along with a postage paid return envelope. The patient should be instructed to call us if he or she has any questions about the study before returning the signed consent form to us through the mail.

Next the patient is scheduled for a telephone interview. The patient is given a choice of 3-hour blocks of time during the following week. Interviewers will be calling patients between 9:00 and noon, 1:00 and 3:00 pm, and 4:00 and 7:00 pm. See Appendix F for a sample schedule form. Five patients may be scheduled for one block of time. The patient is given the 3 hour range rather than a specific time for the call. After choosing a block of time that works best, the patient is given a reminder card (see Appendix G) to take home with our toll free number in case he or she needs to reschedule.

6. Patient Eligibility

Patients who have been selected from the CBOC appointment list for the day will be eligible for the study. Kris Baughman will select a stratified sample of patients from each clinic for a particular day based on the patient's gender, age, and appointment time. She also will take into consideration the number of patients we need to approach in order to get an adequate number of participants, the amount of time it takes to enroll a patient, and the number of research assistants assigned to recruiting that day. Patients who cannot be interviewed in English, who do not pass the clock face competency test, or who are institutionalized will be excluded. The following table shows the age and gender distribution of the projected final sample.

	Age Group	Population Size	RLS Estimated Prevalence (p)	Sample Size (n)
Men	18-30	547	5.0	115
	31-40	1885	8.0	177
	41-50	5271	8.0	177
	51-60	10990	11.0	236
	61-70	11523	11.0	236
	71-80	17719	11.0	236
	81 +	5172	14.0	290
Women	18-50	1313	7.0	157
	51+	1087	14.0	290
			Total	1914

Table 1. Assumptions for sample size estimates.

7. Ethics and Confidentiality

Although the goal of research is to add to the existing knowledge and make findings public, it is important to protect the privacy of the patients participating in the study. Extreme care is taken to ensure that no data are disseminated that can be linked to any particular individual. All information which connects any questionnaire with a patient is removed as soon as the project director transfers the data to the SAS database. This information is retained in locked confidential files. The questionnaires are identified only by numbers.

It is the responsibility of all research assistants to maintain the strict confidentiality of information obtained from patients. Research assistants perform a professional function when they obtain information from a patient. All observations made by research assistants and any information relayed to them by the patient or program staff is privileged. They will not talk about the patient to other people, and will not reveal the patient's names, for any reason, to anyone. Research assistants are expected to maintain professional and ethical standards by keeping this information confidential, between the patient and the project staff.

All project staff will be required to complete the following VAMC training courses:

- a. Protecting Study Volunteers in Research
- b. HIPAA Privacy Training
- c. Good Clinical Practice

8. Building Rapport with Patients

Participating in a research project is a personally revealing process. Patients respond to research assistants as well as to the material covered in the questionnaires. Establishing a relationship with the patient so that he or she feels comfortable with the staff and the program procedures, while maintaining an objective, information-gathering atmosphere throughout the visit is crucial.

Research assistants will be encouraged to build rapport by remembering two essential factors:

- Patients need to view the program as being important and worthwhile.
- Patients need to feel that their interaction with the research staff will be pleasant and satisfying.

Research assistants will be encouraged to try to interest the patient in the study. All patients need to understand that honesty in their responses is important and that their cooperation is essential to the results. Patients should see the questionnaires as a genuine opportunity to express their views. Each research assistant will convey the sense that he or she is an understanding person who accepts what the patient has to say without being critical or judgmental. However, over-friendliness and personal involvement may interfere with the collection of accurate and reliable information. The research

assistant's challenge is to be sensitive to the needs and feelings of the patient while maintaining an objective and neutral attitude.

9. Answering Patient Questions

The following sample answers may be used for possible questions by patients.

Where will the results go? Who will benefit from this research? All patient information will be stored in locked files at the VA, separate from the patient's medical record. The results will be analyzed and presented to government, professional, and community groups interested in learning about sleep problems and health. All results will be presented so that the identities of individual participants are strictly protected, no names will be used. These results should be helpful in identifying the kinds of help or assistance individuals with sleep problems need.

When will I talk to you next? What happens next? We will be calling you for the telephone interview at the time we agreed upon. Then, in a year from now, we will be sending you a questionnaire through the mail. We want to monitor any changes in your sleep patterns and health.

Will I find out about the results of your study? Will I find out how other people did in the study? We will send you a report on the information we collect from the entire group of participants at the end of the study (in about three years). This report will not identify any individuals in the study but will summarize what we found.

Will I find out about my own results in the study? You can contact your physician or health team and request that they contact us for the results.

How is my privacy protected? We protect your privacy by keeping all information regarding your identity in a locked file. Your answers will be kept confidential and will only be used in combination with information from other patients as a group. Your name will not be used in any research reports or articles.

Why are you asking about my education, etc? Many studies have shown that education (or whatever issue concerns the patient) can make a difference in people's lives. Please remember that your answers will be kept confidential and will only be used in combination with information from other patients as a group. You also have the right to refuse to answer any question that makes you uncomfortable.

Why aren't you asking me about (whatever)? There are many factors that can impact people's sleep. Because we must talk to a large number of patients, we have tried to focus on issues that would be common among most people. As a result, we may miss an aspect that you feel is very important. There will be a time at the end of the interview when you can talk about the things you feel may have been missed. We want, very much, to find out as much as we can about the things you feel are important.

What can you do to help me with my sleep problems? It would be best to talk to your primary care doctor to see what he or she would recommend. Your doctor knows most about your overall health and would know best how to help you.

10. Patients at Risk for Suicide

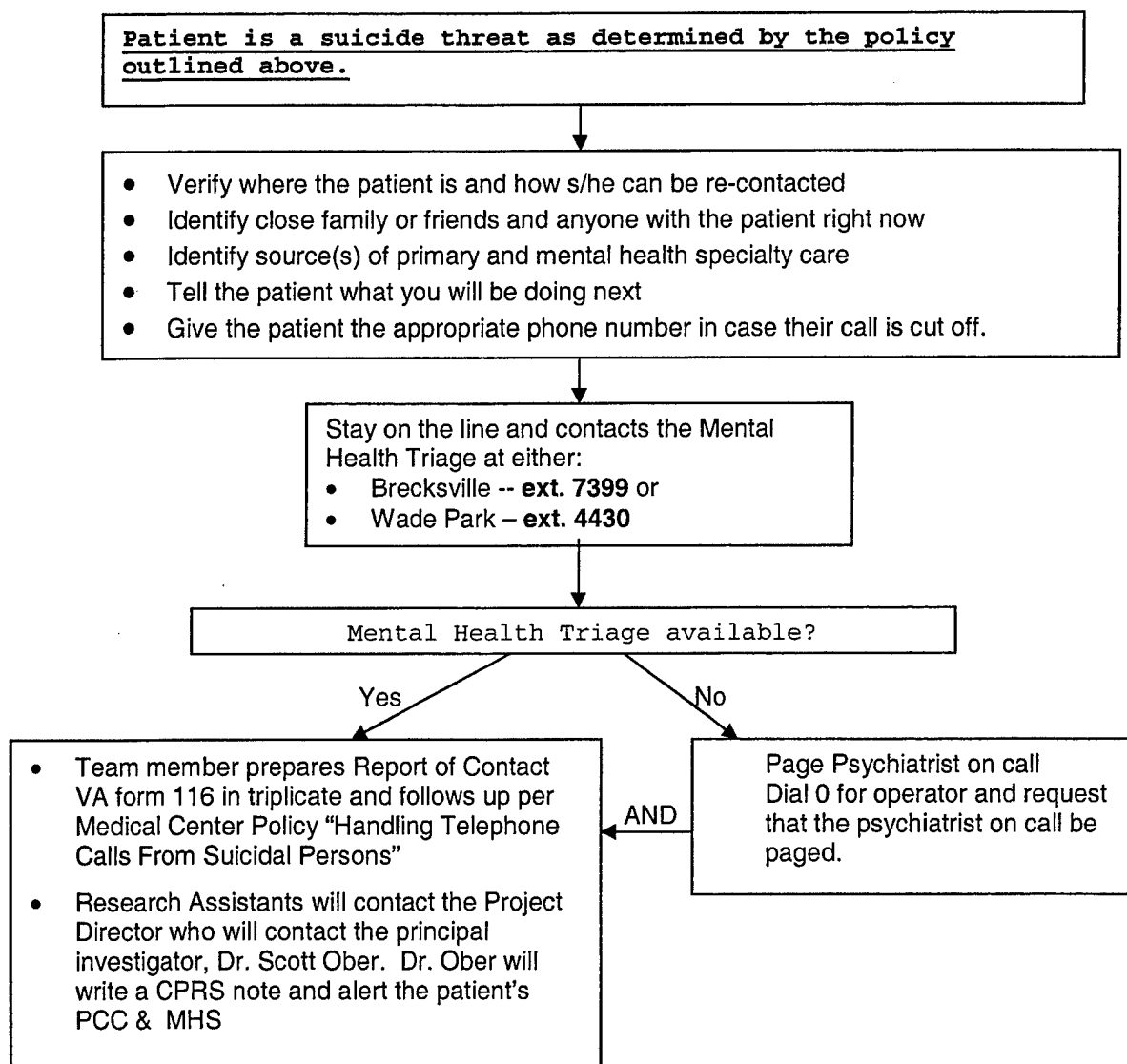
On occasion, a research assistant may encounter a patient who is at significant, near-term risk of suicide and requires professional help.

- If the patient spontaneously mentions any thoughts of suicide (i.e., he or she is contemplating suicide; wants to die; similar statements which make you think he or she is contemplating suicide) or persistent, frequent thoughts of death...

--PLUS--

- The patient answers "yes" to any of the following questions: ***"What you've just told me concerns me, and I'd like to ask you a few (more) questions related to your thoughts and feelings before we continue this interview"***
 - Do you have a suicide plan?
 - Have you attempted suicide in the past?
 - Have you been using alcohol or drugs?
 - Do you have access to a gun?
- Or the patient is substance abusing, has major depression and has not been previously evaluated for any one of these symptoms in mental health (i.e., the patient does not skip out of the depression or substance abuse questions and answers no to the following question, ***"Have you told any of the doctors at the VA about these thoughts/problems?"***

When a staff member identifies a patient at significant, near-term risk of suicide, s/he will follow the algorithm below. These procedures are in accordance with the VA protocol for "Handling Telephone Calls From Suicidal Persons" (see Appendix H).



11. Baseline Telephone Interviews

Patient recruiting and informed consent procedures are discussed in previous sections. Each patient should have a completed recruitment form from the day he or she was recruited. The information is transferred to the first screen of the computerized interview (or the first page of the paper copy of the questionnaire if a computer is not available).

The patient will be telephoned during the block of time scheduled during the recruitment process. If the patient cannot be reached during that time, the patient's recruitment form will be placed in the folder for unfinished interviews. Unfinished interviews should be conducted when an interviewer is finished calling patients during a scheduled 3-hour block or during hours when we are not scheduled to call other participants.

All patients will be asked the following questions:

- The Demographic Questionnaire
- The Insomnia Severity and Epworth Scales
- The RLS Lay Interview
- VA SF 36 – Short form health survey
- The CID-I short form modules for depression, anxiety, alcohol and drug use
- Health Utilization module

See Appendix I for a copy of this questionnaire.

Each patient will be told that the interview will take about 40 minutes. Thus, if the patient does not have time to complete the interview, they should make an appointment for us to call them back.

If any project staff member receives a negative comment or complaint by a participant about the study, the project director should be notified. She will determine if a problem should be brought to the attention of the senior investigators.

12. Confidential List

The names, addresses, and telephone numbers of program participants will be entered in a confidential database. This database will be used to generate mailing labels and keep track of any address or telephone changes. The database also will be used to keep track of the actual dates and projected dates of each interview.

13. Computer File Backup Policy

Interviewers should back up their Epi Info databases every day that they conduct interviews. M:/ is the interviewer's personal drive and S:/ is the study's shared drive. Every day you conduct interviews copy your main file to the S:/ drive and rename the file with the current date.

- Exit Epi Info questionnaire program
- Open Windows Explorer
- Click on the M:/ drive
- Drag your interviewing file from the M:/ drive to the S:/ drive (Left click on mouse and hold down while dragging file)
- Click on the S:/ drive
- Rename the file with your name and current date (Right click on mouse and select rename)

Once a week, Kris will back up the interviewer's files from the S:/ drive to a zip disk and delete old copies of the database on the S:/ drive. Kris will save the following:

- 1 copy (the most current) saved on a zip disk and sent to Scott Ober at Wade Park.
- 1 copy saved on Kris' hard drive and
- 1 copy stays on the network S:/ drive

14. Interview Quality Control:

The project director will listen to each interviewer during two interviews within their first two or three months of data collection. The Quality Control Checklist (see Appendix J) will be completed. At the end of the interview, the project director will review the checklist with the interviewer and provide feedback on all aspects of the interview. If more than two items need improvement, repeat observations will be scheduled. For all interviewers, observations will be scheduled every three months to monitor interviewing skills. The Interview Quality Control Checklists will be kept on file by the project director.

The interviewer must ask the participant's permission to have the project director sit in on the phone call by saying, "To help us get the most accurate information, this call will be monitored by my supervisor. The call won't be recorded but my supervisor will sit in to listen to what I'm saying to you. Is that ok with you?" The interviewer and project director will review the Interview Quality Control Checklist immediately following the telephone interview. Feedback will be provided on all aspects of the interview.

Appendix A Recruitment Brochure
How can I get more information?
Claire Bourguet, PhD is the principal investigator of the study. She can be reached at NEOUCOM at (330) 325-6163 and Bourguet@NEOUCOM.edu.

Scott Ober, MD, MBA is the principal investigator at the Veterans Administration. He can be reached at the Louis Stokes VAMC at (216) 791-3800 ext. 4414 and Scott.Ober@med.va.gov.

Kristin Baughman, PhD is the project coordinator. She can be reached at the Louis Stokes VAMC at (216) 791-3800 ext. 6828 and Kristin.Baughman@med.va.gov.

You or your patients may also wish to contact us through our toll-free number at NEOUCOM.

(800) 686-2511

ext. 5965

Veterans Sleep Study

Louis Stokes Veterans Administration
Medical Center

Documenting the Impact of Sleep Disorders



This study is sponsored by:

The Louis Stokes VA Medical Center
Northeastern Ohio Universities
College of Medicine

The University of Akron

The US Army Medical Research and
Material Command



Louis Stokes VAMC

10000 Brecksville Road
Brecksville, OH 44141
Phone (440) 526-3030

The Veterans sleep study

The purpose of the Veterans Sleep Study is to find out how common sleep problems are among Veterans and to learn more about how sleep affects people's health. In addition, the study will examine how sleep problems affect health care utilization by Veterans. About 2700 VA patients will be invited to participate in a telephone survey. We expect 1900 Veterans to agree to participate.

What does the study involve?

Veterans will be randomly selected from patients attending the CBOC Primary Care Clinics in Northeast Ohio. At each clinic research staff will approach patients who have been pre-selected while the patient is waiting for his or her doctor's appointment.

After describing the study and asking for the patient's participation, the research assistant will assist the patient in completing the informed consent papers and schedule a time for the telephone interview. The recruiting process should take about 15 minutes per patient.

The research assistants will then conduct the interviews over the telephone during the following two weeks. Questions will be asked about:

1. Problems the patient may have had falling asleep or staying asleep
2. Health problems that might keep the patient awake
3. The patient's general physical and mental health
4. The patient's use of drugs and alcohol
5. Doctor's visits and other medical care used in the past month.

In addition, patients will be contacted one year later to participate in a survey we will mail to them. Health information will also be obtained from the patient's medical record if the patient consents.

How your clinic can assist us

Since patients will be recruited from CBOC waiting rooms, we need your help. We want to do everything in our power to keep from interrupting the normal flow of patients between the waiting rooms and the examination rooms.

Depending on the size of your clinic, our research assistants will be at your clinic between 3 and 10 days. During those recruitment days we will be in the waiting room and approaching patients that we have randomly selected from your patient schedules.

We need your help in finding a private place to speak with the patient. The recruitment process should only take about 15 minutes. If the patient is called in to see the doctor before we can finish the consent process, we will attempt to catch the patient after the examination and before the patient leaves the clinic. We want to give the patient every opportunity to ask questions about the study and to feel comfortable in agreeing to participate.

We are committed to not interrupting the normal flow of patients between the waiting rooms and the examination rooms.

We may need your help in identifying patients who have finished their doctor's visit and want to meet with us to ask more questions and complete the informed consent papers.

With your help we will be able to recruit the 1900 veterans needed to conduct a successful study. Sleep disorders can have a powerful impact on people's health and quality of life. Together we can make a difference.

CBOC PROFILE FORM**Date:****CBOC:****Address:****Nurse Manager:****Phone:.****PCAS (Patient care assistance service):****Phone:****Clinic Hours:****Enrollment Preferences:****Areas of privacy:****How to find patient:****How to notify staff of unfinished consent:****Patients who aren't appropriate for study:****Special Notes:****Veterans Sleep Study Contacts:****1-800-686-2511 ext. 5965**

Claire Bourguet, PhD, Principal Investigator
Northeast Ohio University College of Medicine
330-325-6163 Fax: 330-325-5907
e-mail: bourguet@neoucom.edu

Scott Ober, MD MBA Principal Investigator
Louis Stokes Cleveland VA Medical Center
216-791-3800 ext. 4414 Fax: 216-421-3080
e-mail: scott.ober@med.va.gov

Kris Baughman, PhD, Project Coordinator
Louis Stokes Cleveland VA Medical Center
440-526-3030 ext. 6828 Fax: 440-546-2723
e-mail: kristin.baughman@med.va.gov

Recruitment Form

Patient's Name: _____ Gender: Male Female

VA Pt. ID: _____ Age: _____ (if over 90, use 90+)

Time of appointment: _____

Patient's Physician: _____ CBOC: _____

Recruitment Disposition Code: 1. Agreed to participate
2. Refused to participate
3. Could not locate patient at clinic
4. Patient did not have time to talk to us re: enrollment
5. Patient not appropriate for study
6. Could not find private area to speak with patient

Scheduled Interview: Day: _____ Time period: _____

Recruiter Notes: _____

Recruiter's Initials: _____

Epi Info Record #: _____ Interviewer's Initials: _____
Epi Info Record #: _____ Interviewer's Initials: _____
Epi Info Record #: _____ Interviewer's Initials: _____

Call Log

Date of Call	Time of Call	Call Disposition	Notes

Call Log Disposition Codes

LMM = left message on machine

LMP = left message with other person

NA = no answer

PD = phone disconnected

PR = pt refused, do not call back

PTB = pt too busy, call back later

PI = pt ill, call back later

OTH = other (be sure to specify other reason in notes)

Could you draw the face of a clock on this paper? Put the numbers on the face where they belong.

Contour

1. **Contour** - any closed contour, can be circular, oval, square, rectangular, heart shaped etc. Closed contour can mean touching or over lapping.
2. **Size** - size is acceptable if is large enough to contain numbers, can be as big as page. Lines overdrawn so as to interfere with numbers are not acceptable.

Numbers

3. Only 1 to 12. Without adding or omitting numbers. Numbers cannot be repeated.
4. If Arabic numbers, numbers are oriented vertically.
Roman numbers are OK. Roman numbers can be oriented to center or vertically.
Can use IV or IIII for 4. If oriented to center, OK to rotate to place numbers.
5. Must be in correct order.
6. Numbers inside contour (use judgment, 10% of normal respondents place hands outside). OK if other aspects of clock are OK.
7. Numbers in correct position (use judgment). Numbers are correctly placed if not in a position that should be occupied by another number.

What time do you usually go to bed at night? Can you show me that time on the clock?
Draw the hour hand and the minute hand.

Hands

8. Clock has two hands. Arrow heads may or may not be present.
9. Hour target number indicated in some manner. (Could be a tick mark). Location of hour hand can be flexible.
10. Minute target number indicated in some manner. (Could be a tick mark).
11. Correct relative size (minute hand longer).
12. Hands joined or nearly joined at clock center.
13. No superfluous markings. Marks indicating minute intervals are not superfluous.

Center

14. Center indicated or implied by where hand meet or would meet if completely drawn. Should be close to actual center of clock, may not be exact.

Scoring criteria. More than 3 wrong differentiates persons with dementia. If in doubt, e.g. tremor appears to interfere with ability to write. Ask to count back from 100. Stop at 90.

**Thank you for giving me that information. If failure,
"That is all the information that I need from you."**

Subject Name: _____ Date: _____

Title of Study: Prevalence and Outcomes of Restless Legs Syndrome Among VeteransPrincipal Investigator: Scott Ober, M.D. and Claire Bourquet, Ph.D. VAMC: Cleveland (541)DESCRIPTION OF RESEARCH BY INVESTIGATOR

NOTE: The consent form should include the following section headings:

- I. Purpose of the Study
- II. Description of the Study
- III. Inconveniences
- IV. Discomforts/Risks/Side Effects

- V. Benefits
- VI. Alternative Procedure(s)/Treatment(s)
- VII. Use of Research Results
- VIII. Special Circumstances

TO POTENTIAL PARTICIPANTS: Federal regulations require written informed consent before participation in a research study. This is to be certain that research subjects know the nature and risks of the study, as they make a decision to participate or not to participate. You are asked to read the following information and discuss it with the investigator, so that you will be fully informed about this research study and how it may affect you. Your signature on this form means that you have been fully informed and that you freely give your consent to participate.

I. PURPOSE OF THE STUDY:

The purpose of this research study is to find out if sleep problems are common among Veterans and to learn more about how sleep affects people's health.

You are being invited to participate in this research study because you have an appointment to see a doctor at a VA outpatient clinic today.

The research study is sponsored by the Louis Stokes VAMC (LSVAMC), the Northeastern Ohio Universities College of Medicine, and the United States Army Medical Research and Material Command.

2700 VA patients will be invited to participate in this research study.

II. DESCRIPTION OF STUDY:

If you choose to be in the research study, we will ask your permission for four things:

1. We ask your permission to telephone you at home to ask you some questions about problems that you might have with falling asleep or staying asleep; health problems that might keep you awake; and questions about your general physical and mental health; and questions about your use of drugs and alcohol. The interviewer will also ask about doctors visits and other medical care that you have used in the past month.

Cleveland VAMC IRB approved
the use of this version from
50-8-1 to 50-8-1

SUBJECT IDENTIFICATION: ID plate or name (last, first, mid)

Subject's Initials

Subject Name: _____ Date: _____

Title of Study: Prevalence and Outcomes of Restless Legs Syndrome among Veterans.Principal Investigator: Scott Ober, M.D. and Claire Bourquet, Ph.D. VAMC: Cleveland (541)

2. We ask your permission to obtain some information from your VA medical record. The information that we would get is the list of medical problems that you suffer from at this time and information about medical care and prescriptions that you have gotten from the VA in the past month. We will obtain this information from your medical record immediately after the telephone interview.

3. We ask your permission to obtain information from your VA medical record a second time one year from now. At that time we would get the same information that I just listed. That information is the list of medical problems that you suffer from at that time and information about medical care and prescriptions that you have gotten from the VA in the past month.

4. After one year, we would like to send you a questionnaire asking about doctors visits and other medical care that you might have used in the past month. We will also send you a stamped envelope to mail the questionnaire back to us.

III. INCONVENIENCES:

Answering the questions over the telephone could take between one half hour and one hour of your time. One year from now, it might take you about 10 minutes to answer the questionnaire.

IV. DISCOMFORTS / RISKS / SIDE EFFECTS:

There are no special risks to being in the study. Once in a while, someone may become tired or upset while answering the questions. There is also a chance that your health information may be seen by someone not involved in the research.

V. BENEFITS:

You will not directly benefit from participating in this study. Your participation will help medical researchers plan better treatment for people like you who might have sleep problems. This study is not designed to treat any illness or to improve your health.

VI. ALTERNATIVE PROCEDURE(S) / TREATMENT(S):

You are not required in any way to take part in this study.

If there are certain questions that you do not want to answer, you just need to say so, and no one will hold that against you. You can stop the questionnaire at any time by just telling the interviewer.

Cleveland VAMC IRB approved
the use of this version from
1-9-04 to 1-8-05

Subject Name: _____ Date: _____

Title of Study: Prevalence and Outcomes of Restless Legs Syndrome among Veterans.Principal Investigator: Scott Ober, M.D. and Claire Bourquet, Ph.D. VAMC: Cleveland (541)

VII. USE OF RESEARCH RESULTS:

The results of this research study may be published in scientific or medical journals or presented at scientific meetings, but your name and identity will not be used. Any information connecting you to the study will be kept strictly confidential, except as provided by law.

By joining this study, you give the investigators permission to collect data from your medical records about the medical problems you have at this time and about your use of medical care in the past month. You also give the investigators permission to collect the same data from your medical records in one year.

The Institutional Review Boards of the Cleveland VA Medical Center, the Northeastern Ohio Universities College of Medicine, or the US Army Medical Research and Materiel Command may review your medical records as they pertain to this study. It should be noted that representatives of the U.S. Army Medical Research and Materiel Command are eligible to review research records as a part of their responsibility to protect human subjects in research.

VIII. SPECIAL CIRCUMSTANCES:

Financial Considerations

Your participation in this research study will be done at no cost to you, nor will you receive any payment for your participation.

Ending Participation

The investigators may stop your participation in this study without your consent, for example, if they think that it will be in your best interest, or for any other reason.

Compensation for Research-Related Injury

If you sustain physical injury as a direct result of your study participation, medical care will be provided by the Cleveland VA Medical Center at no cost to you. Financial compensation for such things as lost wages, disability, or discomfort due to an injury is not available. You should also understand that this is not a waiver or release of your legal rights. You should discuss this issue thoroughly with the principal investigator before you enroll in this study.

Cleveland VAMC IRB approved
the use of this version from
1-9-04 to 1-8-05

Subject Name: _____ Date: _____

Title of Study: Prevalence and Outcomes of Restless Legs Syndrome among Veterans.Principal Investigator: Scott Ober, M.D. and Claire Bourguet, Ph.D. VAMC: Cleveland (541)

RESEARCH SUBJECTS' RIGHTS: I have read or have had read to me all of the preceding information. Dr./Mr./Ms _____ has explained the study to me and answered all of my questions. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me.

I understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

The results of this study may be published, but I will not be identified in publications by name, photograph, or other identifiers. My records, including my name and results of my participation, may be revealed as required by laws and regulations of state and federal agencies.

If I have any questions about this study or if any problems arise during the study, I can call:

Dr. Scott Ober at 1 888 838 6446 ext. 4847 DURING THE DAY and at 440-646-1231 AFTER HOURS or Dr. Claire Bourguet at 1 800 686 2511 ext. 6163 DURING THE DAY. If any medical problems occur in connection with this study, the Cleveland VA Medical Center will provide emergency care. The telephone number of the Ohio VA Medical Centers is 1 888 838 6446

If I have concerns or questions about my rights as a study member in this research study that the investigator has not answered, I can contact an official of the VA Institutional Review Board for Human Studies through J. Blume at 1 888 838 6446, ext. 4659 or the NEOUCOM IRB through S. Russell at 1 800 686 2511 ext. 6500.

I understand my rights as a subject, and I voluntarily consent to participate in this study. I understand what the study is about and how and why it is being done. I will receive a signed consent form or a photocopy of it. I understand that in signing this consent form I do not waive my legal rights nor release the Cleveland VA Medical Center from liability for negligence.

Subject's Signature _____

Date _____

Subject Name (print) _____

Subject Permanent Address _____

*Signature of Subject's Guardian,
Representative, or Parent

Date _____

Guardian/Representative/Parent (print) _____

Signature of Witness _____

Date _____

Witness (print) _____

Signature of Investigator _____

Date _____

I have received a copy of this consent form

Subject's Initials _____

*Only required if subject is under age or mentally incompetent

Cleveland VAMC IRB approved
the use of this version from

1-9-04 to 1-8-05

VA Department of Veterans Affairs**Authorization for Release of Protected Health Information for Research Purposes**

Subject Name: _____ Date: _____

Title of Study: Prevalence and Outcomes of Restless Legs Syndrome among VeteransPrincipal Investigator: Scott Ober, M.D. and Claire Bourquet, Ph.D. VAMC: Cleveland (541)

The following information explains how your medical information, referred to as "protected health information" or PHI, may be used by the investigators or shared (disclosed) with other people or groups for this research study.

You have been asked to be part of a research study under the direction of Scott Ober, M.D. and his research team. Your PHI is needed for this study in order to find out if sleep problems are common among Veterans and to learn more about how sleep affects people's health.

By signing this document, you will authorize the Veterans Health Administration (VHA) to provide Scott Ober, M.D. and his research team the following PHI about you: the health conditions which you suffer from at this time; and information about your use of health services for one month now and one month a year from now. "Use of health services" means: the number and type of office visits to primary and specialty care physicians, including mental health visits; surgery; hospitalizations; diagnostic tests; use of allied health services, such as physical therapy; and prescription medications.

The information that will be released includes information regarding the following conditions:

- ☒ Drug Abuse
- ☒ Alcoholism
- ☐ Testing for or Infection with Human Immunodeficiency Virus (HIV)
- ☐ Sickle Cell Anemia

The research team may also need to disclose the information to others as part of the study process. The others may include the study sponsor, the US Army Medical Research and Material Command, the LSCDVAMC Institutional Review Board and the NEOUCOM Institutional Review Board that will monitor this study.

If you do not give your authorization for the use of your PHI you will not be able to participate in this research study.

This authorization to use your PHI will expire at the end of the research study.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at the LSCDVAMC or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to

SUBJECT IDENTIFICATION: ID plate or name (last, first, mid)

Subject Name: _____ Date: _____

Title of Study: Prevalence and Outcomes of Restless Legs Syndrome among VeteransPrincipal Investigator: Scott Ober, M.D. and Claire Bourguet, Ph.D. VAMC: Cleveland (541)

continue to participate in the study. This will not affect your right as a VHA patient to treatment or benefits outside the study.

If you revoke this authorization, Scott Ober, M.D. and his research team can continue to use PHI about you that was collected before receipt of the revocation. The research team will not collect PHI about you after you revoke the authorization.

The VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations and all other applicable laws that protect your privacy. We will protect your information according to these laws. Despite these protection, there is a possibility that your information could be used or disclosed in a way that it will no longer be protected. Our Notice of Privacy Practices (a separate document) provides more information on how we protect your information. If you do not have a copy of the Notice, the research team will provide one to you.

I have read this authorization form and have been given the opportunity to ask questions. If I have questions later, I understand I can contact the Privacy Officer at (216) 791-3800 ext. 5300. I will be given a signed copy of this authorization form for my records. I authorize the use of my identifiable information as described in this form.

Signature of Participant_____
Date_____
Signature of Person Authorized To Sign for Participant
(Attach authority to sign, e.g., Power of Attorney)_____
Name of Person Authorized to Sign
for Participant (print)

The Paperwork Reduction Act of 1995 requires us to notify you that this information collection is in accordance with the clearance requirements of section 3507 of the Act. We may not conduct or sponsor, and you are not required to respond to, a collection of information unless it displays a valid OMB number. We expect that the time expended by all individuals completing this form will average 2 minutes. This includes the time to read the instructions, gather the necessary facts and fill out the form. The purpose of this form is to specifically outline the circumstances under which we may disclose data.

The execution of this form does not authorize the release of information other than that specifically described. The information requested on this form is solicited under Title 38, U.S.C. The form authorizes release of information that you specify in accordance with the Health Insurance Portability and Accountability Act, 45 CFR Parts 160 and 164, 5 U.S.C. 552a, and 38 U.S.C. 5701 and 7332. Your disclosure of information requested on this form is voluntary. However if the information, including Social Security Number (SSN) (the SSN will be used to locate records for release) is not furnished completely and accurately, Department of Veterans Affairs will be unable to comply with the request.

Interviewing Schedule Interviewer: _____ Week: _____

	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY
8:00					
9:00 to 12:00					
12:00					
1:00 to 4:00					
4:00					
5:00 to 8:00					
8:00					

Note: Schedule only in blocks not crossed out. Schedule 5 patients for each 3-hour block of time.

Veterans Sleep Study

We will be calling you on: _____

between the hours of _____ and _____

If you need to reschedule,
please leave us a message at
1-800-686-2511 ext. 5965

Veterans Sleep Study

We will be calling you on: _____

between the hours of _____ and _____

If you need to reschedule,
please leave us a message at
1-800-686-2511 ext. 5965

Veterans Sleep Study

We will be calling you on: _____

between the hours of _____ and _____

If you need to reschedule,
please leave us a message at
1-800-686-2511 ext. 5965

Veterans Sleep Study

We will be calling you on: _____

between the hours of _____ and _____

If you need to reschedule,
please leave us a message at
1-800-686-2511 ext. 5965

Veterans Sleep Study

We will be calling you on: _____

between the hours of _____ and _____

If you need to reschedule,
please leave us a message at
1-800-686-2511 ext. 5965

Veterans Sleep Study

We will be calling you on: _____

between the hours of _____ and _____

If you need to reschedule,
please leave us a message at
1-800-686-2511 ext. 5965

Veterans Sleep Study

We will be calling you on: _____

between the hours of _____ and _____

If you need to reschedule,
please leave us a message at
1-800-686-2511 ext. 5965

Veterans Sleep Study

We will be calling you on: _____

between the hours of _____ and _____

If you need to reschedule,
please leave us a message at
1-800-686-2511 ext. 5965

LOUIS STOKES CLEVELAND MEDICAL CENTER POLICY 116A-003
VA MEDICAL CENTER May 31, 2001
10701 East Boulevard, Cleveland, OH 44106
HANDLING TELEPHONE CALLS FROM SUICIDAL PERSONS

1. **PURPOSE.** To define the policy and procedures for handling telephone calls from persons threatening suicide or serious self-inflicted injury.
2. **POLICY.** Handling telephone calls from persons expressing threats of suicide or serious self-inflicted injury will take precedence over duties, which are not related to a life-threatening situation. Responses to such calls are aimed toward helping the caller avoid harming himself or herself or others, getting the caller in contact with an appropriate health care professional, and assuring response by proper authorities.
3. **RESPONSIBILITY.**
 - a. It is the responsibility of any VA Medical Center employee who first determines that a telephone call is from a suicidal person to stay on the telephone with the caller until relieved. The employee will try to keep the person on the line, engaged in conversation, and will not put them on hold. If possible, the employee will enlist the help of others in order to complete the following procedures.
 - b. This responsibility does not extend to operators on the Medical Center switchboard. They are to transfer the call to the Psychiatric Evaluation and Consultation Team at (Brecksville), Extension 7399, or at (Wade Park), Extension 4719. During other than administrative hours, such calls should be directed to the Nursing Supervisor at Brecksville or the Psychiatric Resident on call at Wade Park.
 - c. When attempting to reach a staff member in connection with a call from a suicidal person, the importance and urgency of the call should be clearly stated.
 - d. It is the responsibility of the senior psychiatric evaluation personnel on duty, nursing supervisor, or psychiatric resident on call to respond to any report of a call from a suicidal person by going to where the call was answered, assisting the employee taking the call, and determining when and if to relieve that employee. Transferring calls to other extensions throughout the Medical Center should not be done unless the circumstances warrant incurring the increased risk of the caller hanging up or being disconnected.
 - e. In the absence of a competing emergency, it is the responsibility of anyone else to help when asked. This may mean going to get a medical record or calling someone on a different telephone line to get additional information.
4. **PROCEDURES.**
 - a. The interactions between the employee taking the call, the clinicians involved, and the caller will vary from one call to the next. The following procedures defines the general actions to be taken after receipt of a telephone call from a person threatening to harm himself or herself:
 - (1) The employee who first determines that a telephone call is from a suicidal person should attempt to learn from the caller his or her name, location where the call is originating, and whether or not the caller has done something to harm himself or herself, or is contemplating such action. One method of obtaining the telephone number is to ask for a number where the caller could be called back in case of an inadvertent disconnection or if they have a "bad connection."
 - (2) The employee should attempt to get the attention of a co-worker, while not interrupting the call. If successful in attracting help, the employee should discreetly alert the second employee that she or he is engaged in a conversation with a suicidal person. If the person handling the call cannot attract the attention of a co-worker for help, the employee should be guided by the circumstances in determining if and when to interrupt the call to seek additional help. If it appears that the employee must interrupt the call, it would be most helpful if the name of the caller and the location of the call's origin were determined before leaving the telephone, even for a brief period of time. If an employee must leave to obtain assistance, he or she should return to the call as promptly as possible.
 - (3) The second employee will immediately call the Psychiatric Evaluation and Consultation Team at (Brecksville), extension 7399 or at (Wade Park), extension 4719. For calls after regular administrative hours, contact should be made with the Nursing Supervisor at Brecksville or the Psychiatric Resident on call at Wade Park. The employee making the

notification will give the location of the telephone where the call is being handled and any information learned about the caller thus far, and request that the staff come immediately to the area to assist in the call.

- (4) The Psychiatric Evaluation and Consultation Team staff person will go to where the call was taken. Either personally or through the assistance of another employee, she or he will get whatever information is readily available on the caller. The VISTA computer is the fastest source of patient related information. Since not all patient information is in VISTA, it may be desirable to obtain the medical record as well. In the event the caller is an employee and not a patient, Human Resource Management Service and/or the employee's Service chief can be contacted for home address or other pertinent information.
- (5) The Psychiatric Evaluation and Consultation Team staff person will, to the extent possible, monitor the call and direct the intervention.
- (6) The Psychiatric Evaluation and Consultation Team staff person will notify the patient's primary therapist where applicable, Patient Care Administration Service to assist in information gathering, and Police Service to coordinate contact with outside police and emergency services.
- (7) Response by police will be requested as soon as the location of the caller becomes known. If the caller is on VA property, then the VA Police Service will respond in accord with their policies and procedures. When the call originates off site, the police department in the locality of the call's origin should be contacted. It is preferable that this contact be made by the VA police; however, any employee may make the contact if it is the best course of action under the circumstances.

- b. As soon as possible after the emergency is over, each person participating in the response to the call should complete a report of contact detailing what happened. Copies of all reports of contact should be sent to the individual's supervisor and the Chief of Staff's office at either Brecksville or Wade Park.

5. REFERENCES. None.

6. RESCISSION. This policy rescinds Medical Center Policy 116A-007 "Handling of Telephone Calls from Suicidal Persons" dated November 1, 1998. The date of rescission of this policy is December 31, 2003.
7. FOLLOW-UP RESPONSIBILITY. Chief, Mental Health Care Line. WILLIAM D. MONTAGUE Medical Center Director

Interview Quality Control Checklist

Interviewer: _____

Phone Number: _____

Study Acronym/Database version: _____

Observer: _____ Date: _____

Start time: _____ End time: _____

KEY: S = satisfactory; NI = needs improvement; NA = not applicable**A. Set-Up and Introduction:**

1. Appropriate forms and supplies on hand: _____

2. Introduces himself/herself: _____

3. Explains task (including time frame for interview): _____

Notes: _____

B. Data Collection:

1. Prompts for correct study response: _____

2. Verifies answers when unclear: _____

3. Reads questions loudly and clearly: _____

4. Skips to correct section of questions: _____

Notes: _____

Date discussed: _____

C. Interviewing Technique:

1. Establishes rapport with the participant: _____

2. Uses standard probes: _____

3. Leads the interview: _____

4. Remains neutral throughout interview: _____

5. Adheres to the study-specific script: _____

6. Maintains a comfortable pace:

Notes:

D. Conclusion:

1. Gives patient information about future mail survey:

2. Expresses appreciation:

Notes:

Additional Comments: